



Brussels, **XXX**
[...](2020) **XXX** draft

Annex IIIa to EASA Opinion No 04/2020

COMMISSION DELEGATED REGULATION (EU) .../...

of **XXX**

amending Commission Regulation (EU) No 748/2012 as regards the establishment of safety management systems for design and production organisations as well as the establishment of procedures for the Agency when it carries out its tasks and responsibilities as regards the issuance, maintenance, amendment, suspension and revocation of design certificates, design approvals and design authorisations

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

At the end of 2013, ICAO published the first edition of Annex 19 ‘Safety Management’ (referred to as ‘ICAO Annex 19’). Later, in 2016, ICAO published the second edition of Annex 19. According to Annex 19, the use of a safety management system (SMS) is foreseen for design, production and maintenance organisations.

In addition, Annex II ‘Essential requirements for airworthiness’ to Regulation (EU) 2018/1139 explicitly calls for design, production and maintenance organisations to implement and maintain a management system (MS), including the management of safety risks, and aim for the continuous improvement of that system supported by the establishment of an occurrence-reporting system.

For design and production organisations, Commission Regulation (EU) No 748/2012 already includes organisational requirements that cover some safety management aspects, but the Standards and Recommended Practices (SARPs) from ICAO Annex 19 are regards safety management are not consistently implemented and fully transposed for these organisations into the EU regulatory framework.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In accordance with Article 128(4) of Regulation (EU) 2018/1139, before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. The present draft delegated act was presented to the Air Safety experts group, which includes representatives from the Member States, at its meeting on [...]. The present draft delegated act is based on EASA Opinion No 04/2020 whose contents had been publicly consulted through Notice of Proposed Amendment (NPA) 2019-05 ‘Embodiment of safety management system (SMS) requirements into Part-145 and Part 21’ (RMT.0251 — Phase II), published by EASA on 17 April 2019.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Articles 19 and 62(13) of Regulation (EU) 2018/1139 empower the Commission to adopt delegated acts, in accordance with Article 128 of that Regulation, laying down detailed rules with regard to the necessary features and functionalities related to the airworthiness of aircraft.

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (1), and in particular Articles 19(1) and 62(13) thereof,

Whereas:

- (1) Commission Regulation (EU) No 748/2012 ⁽²⁾ lays down the requirements for the design and production of civil aircraft as well as engines, propellers and parts to be installed therein.
- (2) In accordance with Annex II ‘Essential requirements for airworthiness’ to Regulation (EU) 2018/1139, approved design and production organisations should implement and maintain a management system, appropriate to the type of their activities, to ensure compliance with the essential requirements for airworthiness, manage safety risks and aim for the continuous improvement of that system.
- (3) In accordance with Annex 19 ‘Safety Management’ to the Chicago Convention, the European Union Member States and the European Union Aviation Safety Agency should require approved organisations that design and produce civil aircraft, as well as engines, propellers and parts to be installed therein, to implement a safety management system appropriate to the type of activity undertaken by the organisation and to its size.
- (4) Commission Regulation (EU) No 748/2012 already requires approved design and production organisations to comply with some elements of the management system; however, this management system does not completely cover the Standards and Recommended Practices (SARPs) for such a safety management system established in Annex 19 to the Chicago Convention. Therefore, the missing elements of the management system should be added to the existing requirements.

⁽¹⁾ OJ L 212, 22.08.2018, p. 1.

⁽²⁾ Commission Regulation (EU) No 748/2012 of 3 August 2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations (OJ L 224, 21.8.2012, p. 1).

- (5) In order to ensure a proportionate implementation as well as consistency with the approach used for continuing airworthiness organisations operating in the general aviation domain, design and production organisations, for which an approval is not mandatory according to Commission Regulation (EU) No 748/2012, should not be required to comply with all the elements of the management system.
- (6) All organisations, including those that have their principal place of business outside the European Union, when they design and produce products and parts in accordance with Commission Regulation (EU) No 748/2012, are already required to establish a mandatory and voluntary occurrence-reporting system. However, Regulation (EU) No 748/2012 should be amended to ensure that this occurrence-reporting system is aligned with the principles of Regulation (EU) No 376/2014 ⁽³⁾.
- (7) In addition, the requirements for the European Union Aviation Safety Agency with regard to the tasks related to design certification, oversight and enforcement should be amended.
- (8) A sufficient transition period should be provided for approved design organisations to ensure their compliance with the new rules and procedures introduced by this Regulation.
- (9) The measures provided for in this Regulation are based on Opinion No 04/2020 ⁽⁴⁾, issued by the European Union Aviation Safety Agency in accordance with Article 76(1) of Regulation (EU) 2018/1139.
- (10) Commission Regulation (EU) No 748/2012 should therefore be amended,

HAS ADOPTED THIS REGULATION:

Article 1

Commission Regulation (EU) No 748/2012 is amended as follows:

- (1) in Article 8, the following paragraph 4 is added:
 - ‘4. By way of derogation from points 21.B.433(d)(1) and (d)(2) of Annex I (Part 21), a design organisation that holds a design organisation approval certificate may correct any findings of non-compliance related to point 21.A.239(c) until [*OP please insert date: 2 years after the applicability date*]. If after [*OP please insert date: 2 years after the applicability date*] the organisation has not closed these findings, the Agency shall revoke, limit or suspend in whole or in part the approval certificate.’

Article 2

Annex I (Part 21) to Regulation (EU) No 748/2012 is amended in accordance with Annex I to this Regulation.

⁽³⁾ Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 (OJ L 122, 24.4.2014, p. 18).

⁽⁴⁾ <https://www.easa.europa.eu/document-library/opinions>

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*OP please insert date: 1 year after the date of entry into force*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN